MAY 14 2002

K021023

Section 3
HemosIL Normal Control - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4207

Contact Person:

Carol Marble, Regulatory Affairs Manager
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

March 28, 2002

Name of the Device(s):

HemosIL Normal Control ASSAYED

Classification Name(s):

Common Name	Plasma Coagulation Control
Product Code	81GGN
Regulation Number	21 CFR 864.5425
Classification	Class II

Identification of Predicate Device(s):

K002400	Assess™ Normal Control NOTE: Control was 510(k) cleared as part of analyzer systems, most recently the ACL Advance.

Description of the Device/Intended Use(s):

HemosIL Normal Control ASSAYED is intended for the quality control of coagulation assays in the normal range on IL Coagulation and ELECTRA™ Systems. The normal control is prepared using human citrated plasma from healthy donors.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

HemosIL Normal Control is substantially equivalent to the predicate device in performance, intended use and safety and effectiveness.

Section 3 (Cont.)
HemosIL Normal Control - 510(k) Summary
(Summary of Safety and Effectiveness)

Summary of Performance Data:

A precision study was performed with HemosIL Normal Control over multiple days with multiple runs using specific lots of IL reagents on IL instrumentation:

Analyte	n=	Mean (n=80)	Within-Run %CV
Activated Partial Thromboplastin (APTT) (Seconds)	80	28.0	1.87
Antithrombin (% Activity)	80	110	2.10
Factor V (Extrinsic) (% Activity)	80	96.4	4.47
Factor VIII (Intrinsic) (% Activity)	80	89.6	6.36
Fibrinogen - Clauss (mg/dL)	80	400	2.79
Fibrinogen - PT-Based (mg/dL)	80	329	4.62
Plasmin Inhibitor (% Activity)	40	99	1.05
Plasminogen (% Activity)	40	109	1.38
Protein C (% Activity)	80	114	2.98
Protein S (% Activity)	40	97.8	1.84
Prothrombin Time (PT) (Seconds)	80	10.1	1.58
Thrombin Time (Seconds)	80	13.0	1.54

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 4 2002

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, Massachusetts 02421-3125

Re: k021023
Trade/Device Name: HemosIL Normal Control ASSAYED
Regulation Number: 21 CFR § 864.5425
Regulation Name: Plasma, Coagulation Control
Regulatory Class: II
Product Code: GGN
Dated: March 28, 2002
Received: March 29, 2002

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K021023

Device Names: HemosIL Normal Control ASSAYED

Indications for Use:

HemosIL Normal Control ASSAYED is intended for the quality control of coagulation assays in the normal range on IL Coagulation and ELECTRA™ Systems. The normal control is prepared using human citrated plasma from healthy donors.

Values for all analytes are within the normal range.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021023

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)